A01020B

REMARKS

Claims 1-36 are pending in this application. The Examiner contends that this Application contains the following (138) inventions or groups of inventions, which allegedly are distinct:

Group I-X, claims 1-16, drawn to a gene expression modulation system comprising two expression vectors wherein the LBD of the first polypeptide is encoded by ONE of the following polynucleotides: SEQ ID NO: 1-10;

Group XI-XX, claims 1-16, drawn to gene expression modulation system comprising two expression vectors wherein the LBD of the first polypeptide is ONE of the following polypeptides: SEQ ID NO: 11-20;

Group XXI-XXX, claims 1-16, drawn to gene expression modulation system comprising two expression vectors wherein the LBD of the second polypeptide is encoded by ONE of the following polynucleotides: SEQ ID NO: 21-30;

Group XXXI-XL, claims 1-16, drawn to gene expression modulation system comprising two expression vectors wherein the LBD of the second polypeptide is ONE of the following polypeptides: SEQ ID NO: 1-10;

Group XLI-LXVIII, claims 17-20, drawn to a gene expression cassette wherein the polynucleotide sequence comprises ONE of SEQ ID NO: 41, 43, 45, 47, 49, 51, 53, 1-10, 21-30;

Group LXIX-LXXXXIV, claims 17-20, drawn to a gene expression cassette wherein the encoded polypeptide is ONE of the following: SEQ ID NO: 42, 44, 46, 48, 50, 52, 54, 11-20, 31-40;

Group LXXXXV-CXV, claims 21-26, drawn to an isolated polynucleotide comprising one of the following: SEQ ID NO: 1-10, 21-30;

Group CXVI-CXXXVI, claims 27-29, drawn to a polypeptide comprising ONE of the following: SEQ ID NO: 11-20, 31-40;

Group CXXXVII, claims 30-32, drawn to a method of modulating the expression of a gene with a ligand;

Group CXXXVIII, claims 35-36, drawn to a transgenic non-human animal.

The Examiner suggested that the inventions listed as Groups I-CXXXVIII are independent and distinct as they are products which possess characteristic differences in structure and function, as evidenced by the difference sequences set forth for each Group. The Examiner further suggests that the differences in the structure of each Group, a search of art on one Group would not reveal art on the other Groups, thus

imposing a burden to search on the Examiner. Further the Examiner states that the Groups are distinct given that the product as claimed can be used in a materially different process of using that product, and specifically that the polynucleotide of Groups I-CXXXVI can be used as hybridization probes.

In reply, and solely to be responsive to the Examiner's requirement, Applicants provisionally elect Groups I-X, claims 1-16, drawn to a gene expression modulation system comprising two expression vectors wherein the LBD of the first polypeptide is encoded by SEQ ID NO: 3, with traverse. Applicants submit that the claims of Groups I-LXXXXIV are related, disclosed as capable of use together, and drawn to a single invention.

Under 35 U.S.C. § 121, restriction may be required if "two or more independent and distinct inventions are claimed in one application." According to the interpretation provided in MPEP § 802.01, the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect...." The term "distinct" is defined in MPEP § 801.02 as meaning that "two or more subjects as disclosed are related... but are capable of separate manufacture, use or sale as claimed, and ARE PATENTABLE (novel and unobvious) OVER EACH OTHER..." (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

The mere existence of two or more independent or distinct inventions in one application is not sufficient to justify a restriction requirement.

According to the guidelines in MPEP § 803, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Accordingly, Groups I- X are related to gene expression modulation system comprising two expression vectors wherein the LBD of the first polypeptide is encoded by ligand binding domain from a nuclear receptor. However, the Examiner has narrowed and restricted claims 1-16 to specifically a ligand binding domain encoded by one of the following polynucleotides: SEQ ID NO: 1-10. Likewise, the Examiner has

narrowed and restricted claims 1-16 to specifically a second ligand binding domain encoded by one of the following polynucleotides SEQ ID NOs: 21-30.

Thus, all of these claims involve a fundamental determination of the novelty of a gene expression modulation system comprising two expression vectors, in which the specifics of the gene expression cassettes have been defined. To the extent that this determination would be made, it is submitted that a preponderantly coextensive search would result. In particular, an exhaustive search for a gene expression modulation system comprising two expression vectors comprising SEQ ID NO: 1 of Group I would encompass the gene expression modulation system comprising two expression vectors comprising SEQ ID NOs: 2, 3, 4 or 5 of Groups II-V, respectively. Performing an entire search covering a gene expression modulation system comprising two expression vectors whether it is utilizing SEQ ID NO: 1, 2, 3, 4 or 5, all of which are classified in class 435, subclass 320.1 as indicated by the Examiner, is less burdensome on the Examiner than separate searches, which necessarily involve duplication of searching efforts.

The claims are directed to a gene expression modulation system, and the gene expression modulation system of claims 1-16 is limited in the LBD, to nuclear receptor ligand binding domains. In regards to SEQ ID NOs: 1-10, Applicants have provided specific sequences for the LBD that are related. SEQ ID NOs: 1-10 are all ecdysone receptor (EcR) domains. Specifically SEQ ID NOs: 1-5 are all CfEcR domains, and SEQ ID NOs: 5-10 are DmEcR domains and therefore the examiners indication that a search of art on one group would not reveal art on the other groups is inaccurate. Likewise SEQ ID NOs: 21-30 are all retinoid X receptors (RXR) domains, and again would all be revealed during the same search. In addition, it is well known in the art that the LBD among nuclear receptors is conserved and that the domains of the receptors are modular.

Applicants respectfully submit that prosecution of the claims of Groups I-LXXXXIV designated by the Examiner in the present Application is appropriate. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added). The groups designated by the Examiner fail to define products with properties so distinct as to warrant separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application. The suggestion by the Examiner that the claims are distinct given that the product as claimed can be used in a materially

different process of using that product, and specifically that the polynucleotide of Groups I-CXXXVI can be used as hybridization probes, is an insufficient distinction given that a multitude of polynucleotide sequences can be used as a hybridization probe.

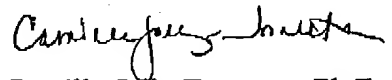
Thus, Applicants submit that the search and examination of claims 1-20 can be made without serious burden. Division of the instant invention into 138 groups presents undue burden to the Applicants' "..exclusive Right to their respective Writings and Discoveries." (Constitution, Article 1, section 8, clause 8) Applicants respectfully submit that conjoint examination and inclusion of these claims of the present application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction is believed to be in order.

Conclusion

Applicants respectfully submit that claims 1-20 are drawn to a single general inventive concept as defined in 37 CFR § 1.1. Thus, the inventions of Groups I-LXXXXIV as hereinabove defined, are not independent, and are classified in the same class for searching purposes, and the search of the claims of these groups does not impose an undue search burden on the Examiner.

Applicants submit respectfully that the Examiner has provided insufficient reasons in support of a restriction between the inventions of Groups I- LXXXXIV. In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the finding of lack of relatedness between the claims of Groups I-LXXXXIV. All of these claims should fairly be examined in a single application. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications directed to the subject matter of the non-elected claims. If a telephone interview would be of assistance in advancing prosecution of this application, Applicants' agent invites the Examiner to contact her at (610) 650-8734 ext. 104.

Respectfully submitted,



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